K121305

SEP 25 2012

5 510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Armstrong Industries, Inc.
Contact Person:	Ralph Armstrong, President and CEO
Official Correspondent:	John Stanley, Vice President and General Manager
Establishment Registration Number:	K121305
Performance Standard(s):	Guidance Document for Powered Muscle Stimulator 510(k), issued June 9, 1999.

Name of Device:

Trade Name:	Sterling Medical Impulse 3 Stimulator
Common Name:	TENS, NMES, and INF External stimulator
Regulation Numbers:	21 CFR 882.5890
Regulation Class:	II
Panel Name:	Neurology
Product Code:	GZJ, IPF, LIH

Identification of Predicate Device(s):

Manufacturer	Device	510(k) Number
Biomedical Life Systems, Inc.	BMLS04-1 (QuadStar II)	K041388
Newwave Medical, LLC	Smartwave IF 2000	K003631
Newwave Medical, LLC	Smartwave MS 2000	K041063
Armstrong Industries, Inc.	Sterling TENS	K891118

Intended Use Statement

The Impulse 3, when in interferential stimulation (INF) mode, may be used for symptomatic relief and management of chronic (long-term) intractable pain and/or as an adjunctive treatment in the management of postsurgical and post-traumatic acute pain.

The Impulse 3, when in neuromuscular stimulation (NMES) mode, may be used as therapeutic adjunct for: prevention or retardation of muscle disuse atrophy; relaxation of muscle spasm; muscle reeducation; maintaining and increasing the range of motion; increasing local blood

K121305

circulation and as immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.

The Impulse 3, when in Transcutaneous Electrical Nerve Stimulation (TENS) mode, may be used for the symptomatic relief and management of chronic (long-term) intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

This is a prescription device and should be used under medical supervision.

Device Description

The Impulse 3 is a portable two channel, battery operated combination electrical neuromuscular stimulator (NMES), interferential stimulator (INF), and transcutaneous electrical nerve stimulator (TENS) unit for pain control, and muscle stimulation. This device, supporting symmetric biphasic, pulsed sine, and asymmetrical biphasic waveforms can be used with the preprogrammed protocols or can be manually configured. A graphical display is provided to provide the user a verbose interface to assist in programming the configurable protocols.

The device is supplied with electrodes and electrode leads, non-replaceable batteries, wall adapter, instruction manual, and carrying case.

Predicate Device Comparison

The Impulse 3 unit has similar intended use, operating principles, and modes of operation. Based on the predicate product comparison, Sterling Medical has determines that no new issues of safety and effectiveness have been raised with this 510(k) submission.

Comparison to the 510(k) Cleared Predicate Devices:

Parameter	This submission	Predicate device	Predicate device	Predicate device	Predicate device
510(k) Number	K121305	K041388	K041063	K891118	K003631
Device Name and Model	Sterling Medical Impulse 3	QuadStar II	Smartwave MS 2000	Sterling TENS	Smartwave IF 2000
Manufacturer	Armstrong Industries, Inc.	BioMedical Life Systems, Inc.	Newwave Medical, LLC	Armstrong Industries, Inc.	Newwave Medical, LLC
Primary Power Source: Number, Size, and Type of Batteries	2x 750mA, 3.7V, LC14500, Li-ion, rechargeable, not user replaceable	4x AA Batteries, LR6	9V Battery	9V Battery	9V Battery
Optional Power Source and Battery Charger	Wall adapter, In: 100-240vac, 50-60Hz, Out: 9V, 1.3A, UL60601 approved	Wall adapter, In: 120vac, 60Hz, Out: 9V, 1.0A	Wall adapter, In: 100 - 120vac, 50-60Hz, Out: 9V, 1.0A	N/A	Wall adapter, In: 100 - 120vac, 50-60Hz, Out: 9V, 1.0A
Method of Line Current Isolation	Transformer coupled	-	Transformer coupled	-	-
Patient Leakage Current - Normal Condition	7µA	11µA	3.2µA	N/A	3.2µA

K121305

- Single fault condition	98µA	116µA	6.5µA		6.5µA
Average DC current through electrodes when device is on but no pulses are being applied (µA)	1µA	1µA	1µA	1µA	1µA
Number of Output Modes	3, TENS, NMES, and INF	3, TENS, NMES, and INF	1, NMES	1, TENS	1, INF
Number of output channels	2	4	2	2	2
Output Channels: Synchronous or Alternating?	TENS – Synchronous INF – Synchronous NMES - Both	TENS – Synchronous INF – Synchronous NMES - Both	NMES – Both	TENS – Synchronous	INF – Synchronous
Output Channels: Method of Channel isolation	Transformer Coupled	Transformer Coupled	Transformer Coupled	Transformer Coupled	Transformer Coupled
Regulated Current or Regulated Voltage?	Regulated Current	Regulated Current	Regulated Current	Regulated Current	Regulated Current
Software/Firmware/Microprocessor Control?	Yes	Yes	Yes	Yes	Yes
Automatic Overload Trip?	No	No	No	No	No
Automatic No-Load Trip?	Yes, If the unit is not used, it will turn itself off after 1 minute.	No	Yes, If the unit is not used, it will turn itself off after 10 minutes.	No	Yes, If the unit is not used, it will turn itself off after 10 minutes.
Automatic Shut Off?	Yes, the unit turns off after the prescribed program.	Yes, the unit turns off after the prescribed program.	Yes, the unit turns off after the prescribed program.	Yes, the unit turns off after the prescribed program.	Yes, the unit turns off after the prescribed program.
User Override Control?	Yes, the user can turn the unit off	Yes, the user can turn the unit off	Yes, the user can turn the unit off	Yes, the user can turn the unit off	Yes, the user can turn the unit off
Indicator Display: On/Off Status?	Yes	Yes	Yes	Yes	Yes
Indicator Display: Low Battery?	Yes	Yes	Yes	Yes	Yes
Indicator Display: Voltage/Current Level?	Yes	Yes	Yes	Control dials are numbered	Yes
Timer Range (minutes)	1 to 60 minutes	1 to 60 minutes	1 to 60 minutes	-	1 to 60 minutes
Compliance with Voluntary Standards?	-	-	-	-	-
Compliance with 21 CFR 898?	Yes	Yes	Yes	-	Yes
Weight (lb., oz)	6.50 oz.	11.4 oz.	6.24 oz.	4.48 oz.	6.24 oz.
Dimensions (in.) [W x H x D]	3.1" x 4.8" x 1.3"	6.3" x 2.75" x 1.25"	4.7" x 2.8" x 1.0"	3.66" x 2.44" x 1.10"	4.7" x 2.8" x 1.0"
Housing Materials and Construction	ABS 94 HB Plastic Body With Molded Rubber Sides	Plastic	ABS plastic injection molded	Plastic	ABS plastic injection molded

Table for the Comparison of Output Specifications for TENS Mode:

Parameter	Impulse 3	QuadStar II	Smartwave MS 2000	Sterling TENS	Smartwave IF 2000
Mode or Program Name	TENS	TENS	N/A	TENS	N/A
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed asymmetrical biphasic	Pulsed asymmetrical biphasic		Pulsed assymetrical biphasic	
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular		Rectangular	
Maximum Output Voltage (volts)(+/- 5%)	40.6V @ 500Ω 50.2V @ 2kΩ 53.4V @ 10kΩ	48V @ 500Ω 86V @ 2kΩ 96V @ 10kΩ		27.5V @ 500Ω	
Maximum Output Current (specify units) (+/- 5%)	81.3mA @ 500Ω 25.1mA @ 2kΩ 5.3mA @ 10kΩ	96mA @ 500Ω 43mA @ 2kΩ 9.6mA @ 10kΩ		55mA @ 500Ω	
Duration of primary (depolarizing)	50 to 300µs in	10 to 250µs in		50 to 450µs, >	

K121305

phase (µs)	steps of 5µs	steps of 5µs		300µs limits Voltage	
Pulse Duration (µs)	50 to 300µs in steps of 5µs	10 to 250µs in steps of 5µs		50 to 450µs, > 300µs limits Voltage	
Frequency (Hz) [or Rate (pps)]	1 to 120 pps in steps of 1 pps	1 to 120 pps in steps of 1 pps		1 to 120 pps	
For multiphasic waveforms only: Symmetrical phased?	No	No		No	
For multiphasic waveforms only: Phase Duration (include units) (state range, if applicable)(both phases, if asymmetrical)	2ms	20 to 500µs		100 to 1000µs	
Net Charge (microcoulombs (µC) per pulse (If zero, state method of achieving 0 net)	0 net DC, + and – pulses cancel	0 net DC, + and – pulses cancel		0 net DC, + and – pulses cancel	
Maximum Phase Charge (µC)	21.7µC @ 500Ω	24.0µC @ 500Ω		16.5µC	
Maximum Current Density (mA/cm^2, r.m.s.)	0.70mA/cm^2 @ 500 Ω	0.74mA/cm^2 @ 500 Ω		0.42mA/cm^2 @ 500 Ω	
Maximum Average Current (average absolute value), mA	2.61mA	3.60mA		1.98mA	
Maximum Average Power Density (W/cm^2), (using smallest electrode conductive surface area)	4.81mW/cm^2	6.91mW/cm^2		2.18mW/cm^2	
Burst Mode: Pulses per burst	7	8		7	
Burst Mode: Bursts per second	2	2		2	
Burst Mode: Burst duration (seconds)	0.085ms (7 pulses @ 85Hz)	0.250ms (8 pulses @ 32Hz)		0.085ms (7 pulses @ 85Hz)	
Burst Mode: Duty Cycle	0.42%	0.4%		0.42%	
Burst Mode: ON Time (seconds)	If selected, burst mode is constant	If selected, burst mode is constant		If selected, burst mode is constant	
Burst Mode: OFF Time (seconds)	N/A	N/A		N/A	
Effect on Maximum Phase Charge (representative) as battery voltage varies from 5.5V to 8.4V	None, output not affected by battery variations				
Effect on Maximum Phase Charge (representative) as charger voltage varies from 6.75V to 11.25V, no batteries.	None, output not affected by battery variations				
Additional Features (specify, if applicable)					

Table for the Comparison of Output Specifications for INF Mode:

Parameter	Impulse 3	QuadStar II	Smartwave MS 2000	Sterling TENS	Smartwave IF 2000
Mode or Program Name	INF	INF	N/A	N/A	INF
Waveform (e.g., pulsed monophasic, biphasic)	Symmetrical biphasic	Symmetrical biphasic			Symmetrical biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)	Sinusoidal	Square			Sinusoidal
Maximum Output Voltage (volts)(+/- 5%)	26.7V @ 500Ω 33.2V @ 2kΩ 35.4V @ 10kΩ	17.1V @ 500Ω 26.4V @ 2kΩ 29.2V @ 10kΩ			32.4V @ 500Ω 38.0V @ 2kΩ 40.6V @ 10kΩ
Maximum Output Current (specify units) (+/- 5%)	53mA @ 500Ω 16.6mA @ 2kΩ 3.5mA @ 10kΩ	34mA @ 500Ω 13.2mA @ 2kΩ 2.9mA @ 10kΩ			66mA @ 500Ω 19.1mA @ 2kΩ 4.1mA @ 10kΩ
Duration of primary (depolarizing) phase (µs)	125µs	125µs			125µs
Pulse Duration (µs)	250µs	250µs			250µs
Frequency (Hz) [or Rate (pps)]	4000Hz – 4150Hz in steps	4000Hz – 4150Hz in steps			4000Hz – 4150Hz in steps

K121305

	of 1Hz	of 1Hz			of 1Hz
For multiphasic waveforms only: Symmetrical phased?	Yes	yes			Yes
For multiphasic waveforms only: Phase Duration (include units) (state range, if applicable)(both phases, if symmetrical)	250µs	250µs			250µs
Net Charge (microcoulombs (µC) per pulse (If zero, state method of achieving zero net charge)	0 net DC, + and – pulses cancel	0 net DC, + and – pulses cancel			0 net DC, + and – pulses cancel
Maximum Phase Charge (µC)	4.72µC @ 500Ω	4.28µC @ 500Ω			5.73µC @ 500Ω
Maximum Current Density (mA/cm^2, r.m.s.)	1.92mA/cm^2 @ 500Ω	1.37mA/cm^2 @ 500Ω			1.83mA/cm^2 @ 500Ω
Maximum Average Current (average absolute value), mA	37.8mA	34.2mA			45.8mA
Maximum Average Power Density (W/cm^2), (using smallest electrode conductive surface area)	36.3mW/cm^2	23.4mW/cm^2			42.0mW/cm^2
Burst Mode: Pulses per burst	N/A	N/A			N/A
Burst Mode: Bursts per second	N/A	N/A			N/A
Burst Mode: Burst duration (seconds)	N/A	N/A			N/A
Burst Mode: Duty Cycle	N/A	N/A			N/A
Burst Mode: ON Time (seconds)	N/A	N/A			N/A
Burst Mode: OFF Time (seconds)	N/A	N/A			N/A
Effect on Maximum Phase Charge (representative) as battery voltage varies from 5.5V to 8.4V	None, output not affected by battery variations				
Effect on Maximum Phase Charge (representative) as charger voltage varies from 6.75V to 11.25V, no batteries.	None, output not affected by battery variations				
Additional Features (specify, if applicable)					

Table for the Comparison of Output Specifications for NMES AC Mode:

Parameter	Impulse 3	QuadStar II	Smartwave MS 2000	Sterling TENS	Smartwave IF 2000
Mode or Program Name	NMES	NMES	NMES	N/A	N/A
Waveform (e.g., pulsed monophasic, biphasic)	Pulsed symmetrical biphasic (AC)	Pulsed symmetrical biphasic (AC)	Pulsed symmetrical biphasic (AC)		
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Rectangular		
Maximum Output Voltage (volts)(+/- 5%)	26.4V @ 500Ω 36.4V @ 2kΩ 40.8V @ 10kΩ	32V @ 500Ω 60V @ 2kΩ 66.4V @ 10kΩ	28.6V @ 500Ω 35.5V @ 2kΩ 38.3V @ 10kΩ		
Maximum Output Current (specify units) (+/- 5%)	53mA @ 500Ω 18.2mA @ 2kΩ 4.1mA @ 10kΩ	64mA @ 500Ω 30.0mA @ 2kΩ 6.6mA @ 10kΩ	57.2mA @ 500Ω 17.8mA @ 2kΩ 3.8mA @ 10kΩ		
Duration of primary (depolarizing) phase (µs)	50 to 300µs in steps of 5µs	50 to 400µs in steps of 5µs	50 to 300µs in steps of 50µs		
Pulse Duration (µs)	50 to 300µs in steps of 5µs	50 to 400µs in steps of 5µs	50 to 300µs in steps of 50µs		
Frequency (Hz) [or Rate (pps)]	1 to 120 pps in steps of 1 pps	1 to 120 pps in steps of 1 pps	1 to 120 pps in steps of 1 pps		
For multiphasic waveforms only: Symmetrical phased?	Yes	Yes	Yes		

K121305

For multiphasic waveforms only: Phase Duration (include units) (state range, if applicable)(both phases, if asymmetrical)	Second phase identical in width and shape but opposite polarity.	Second phase identical in width and shape but opposite polarity.	Second phase identical in width and shape but opposite polarity		
Net Charge (microcoulombs (μC) per pulse (If zero, state method of achieving zero net charge)	Zero net DC, + and – pulses cancel	Zero net DC, + and – pulses cancel	Zero net DC, + and – pulses cancel		
Maximum Phase Charge (μC)	31.7μC @ 500Ω	32.0μC @ 500Ω	34.3μC @ 500Ω		
Maximum Current Density (mA/cm^2, r.m.s.)	0.72mA/cm2 @ 500 Ω	0.63mA/cm^2 @ 500 Ω	0.62mA/cm^2 @ 500 Ω		
Maximum Average Current (average absolute value), mA	3.8mA	3.84mA	4.13mA		
Maximum Average Power Density (W/cm^2), (using smallest electrode conductive surface area)	5.11mW/cm2	4.92mW/cm^2	4.74mW/cm^2		
Burst Mode: Pulses per burst	N/A	N/A	N/A		
Burst Mode: Bursts per second	N/A	N/A	N/A		
Burst Mode: Burst duration (seconds)	N/A	N/A	N/A		
Burst Mode: Duty Cycle	N/A	N/A	N/A		
Burst Mode: ON Time (seconds)	1 to 99 seconds	0 to 99 seconds	1 to 99 seconds		
Burst Mode: OFF Time (seconds)	0 to 99 seconds	0 to 99 seconds	0 to 99 seconds		
Effect on Maximum Phase Charge (representative) as battery voltage varies from 5.5V to 8.4V	None, output not affected by battery variations				
Effect on Maximum Phase Charge (representative) as charger voltage varies from 6.75V to 11.25V, no batteries.	None, output not affected by battery variations				
Additional Features (specify, if applicable)					

Table for the Comparison of Output Specifications for NMES Russian Mode:

Parameter	Impulse 3	QuadStar II	MS2000	Sterling TENS	Smartwave IF 2000
Mode or Program Name	NMES	NMES	NMES	N/A	N/A
Waveform (e.g., pulsed monophasic, biphasic)	Gated symmetrical biphasic (Russian)	Does not support	Gated symmetrical biphasic (Russian)		
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular		Rectangular		
Maximum Output Voltage (volts)(+/- 5%)	26.4V @ 500Ω 36.4V @ 2kΩ 40.8V @ 10kΩ		28.7V @ 500Ω 34.6V @ 2kΩ 36.6V @ 10kΩ		
Maximum Output Current (specify units) (+/- 5%)	53mA @ 500Ω 18.2mA @ 2kΩ 4.1mA @ 10kΩ		57mA @ 500Ω 17.3mA @ 2kΩ 3.7mA @ 10kΩ		
Duration of primary (depolarizing) phase (μs)	200μs		200μs		
Pulse Duration (μs)	400μs		400μs		
Frequency (Hz) [or Rate (pps)]	50Hz		50Hz		
For multiphasic waveforms only: Symmetrical phased?	Yes		Yes		
For multiphasic waveforms only: Phase Duration (include units) (state range, if applicable)(both phases, if asymmetrical)	Second phase identical is width and shape but opposite polarity.		Second phase identical is width and shape but opposite polarity.		
Net Charge (microcoulombs (μC) per	Zero net DC, +		Zero net DC, +		

K121305

pulse (If zero, state method of achieving zero net charge)	and – pulses cancel		and – pulses cancel		
Maximum Phase Charge (μC)	21.1μC @ 500Ω		23.0μC @ 500Ω		
Maximum Current Density (mA/cm^2, r.m.s.)	1.9mA/cm2 @ 500Ω		1.6mA/cm^2 @ 500Ω		
Maximum Average Current (average absolute value), mA	26.4mA		28.7mA		
Maximum Average Power Density (W/cm^2), (using smallest electrode conductive surface area)	35.5mW/cm2		33.0mW/cm^2		
Burst Mode: Pulses per burst	50		50		
Burst Mode: Bursts per second	50		50		
Burst Mode: Burst duration (seconds)	10mSec		10mSec		
Burst Mode: Duty Cycle	50%		50%		
Burst Mode: ON Time (seconds)	1 to 99 seconds		1 to 99 seconds		
Burst Mode: OFF Time (seconds)	0 to 99 seconds		0 to 99 seconds		
Effect on Maximum Phase Charge (representative) as battery voltage varies from 5.5V to 8.4V	None, output not affected by battery variations				
Effect on Maximum Phase Charge (representative) as charger voltage varies from 6.75V to 11.25V, no batteries.	None, output not affected by battery variations				
Additional Features (specify, if applicable)					

Performance Summary (non-clinical)

Compliance to applicable voluntary standards includes IEC 60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety, 1988, Amendment 1, 1991-11, Amendment 2, 1995.

Testing has been included in the premarket notification to demonstrate equivalence to the predicate devices and meets the "Guidance Document for Powered Muscle Stimulators," dated June 9, 1999.

Conclusion

The Sterling Medical Impulse 3 combination stimulator has the same intended use and similar technological characteristics as the BMLS04-1 (K041388) marketed by Biomedical Life Systems, Inc. In addition, the Impulse 3 supports three modes and has the same intended use and similar technological characteristics as the single mode predicate devices. The Impulse 3 in neuromuscular (NMES) mode has the same intended use and similar technological characteristics as the MS 2000 (K041063) marketed by Newwave Medical, LLC. The Impulse 3 in interferential (INF) mode has the same intended use and similar technological characteristics as the IF 2000 (K003631) marketed by Newwave Medical, LLC. The Impulse 3 in transcutaneous electrical nerve stimulator (TENS) mode has the same intended use and similar technological characteristics as the Sterling TENS (K891118) marketed by Armstrong Industries, Inc.

K121305

Bench testing contained in this submission demonstrates that any differences in their technological characteristics to not raise any new questions of safety or effectiveness. Therefore, the Sterling Medical Impulse 3 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 25 2012

Armstrong Industries, Inc.
c/o Mr. Ralph Armstrong
President and CEO
7290 Virginia Pkwy, Suite 3000
McKinney, TX 75071

Re: K121305
Trade/Device Name: Sterling Medical Impulse 3 Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: II
Product Code: GZJ, IPF, LIH
Dated: Not Dated
Received: September 6, 2012

Dear Mr. Armstrong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Indications for Use Statement

510(k) Number (if known): __K121305_____

Device Name: Sterling Medical Impulse 3 Stimulator

Indications for Use:

Interferential Stimulation (INF) is used for symptomatic relief and management of chronic (long-term) intractable pain and/or as an adjunctive treatment in the management of postsurgical and post-traumatic acute pain.

External electrical neuromuscular stimulation (NMES) using biphasic output is indicated as therapeutic adjunct for: prevention or retardation of muscle disuse atrophy; relaxation of muscle spasm; muscle reeducation; maintaining and increasing the range of motion; increasing local blood circulation and as immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.

Transcutaneous Electrical Nerve Stimulation (TENS) is used for the symptomatic relief and management of chronic (long-term) intractable pain and/or as an adjunctive treatment in the management of post-surgical and post-traumatic acute pain problems.

Prescription Use _X__ AND/OR Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Page 1 of 1

510(k) Number K121305